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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,566	02/15/2002	Brian Brockway	22570-023001	3298

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EXAMINER	
NASSER, ROBERT L	
ART UNIT	PAPER NUMBER
3735	
MAIL DATE	DELIVERY MODE
12/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/077,566	BROCKWAY ET AL.	
	Examiner	Art Unit	
	Robert L. Nasser	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17, 44, 48--52, 55, and 60-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17, 44, 48--52, 55, and 60-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-12, 50, 63, and 65-68 rejected under 35 U.S.C. 102(b) as anticipated by Pohndorf et al 5353800, in the alternative, under 35 U.S.C. 103(a) as obvious over Pohndorf et al.

Claims 1, 3-12 , 50, 63, and 65-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Pohndorf et al 5,353,800. Pohndorf teaches a method of implanting a pressure measurement device in the heart of a patient comprising providing a pressure

sensor assembly 10 including a pressure transducer 14 and a pressure transmission catheter 16, where the catheter has a distal end portion having an opening with a barrier, i.e. a membrane (see column 4, lines 26-30). In addition, the pressure transducer is proximal to the distal end portion. The method further includes positioning the catheter across a heart wall, with the opening in chamber of the heart (see figure 3 and the associated discussion). It is clear that the coiled catheter is more flexible than the proximal end where cap 30 is, as an elongate member is more flexible than a fluid filled cap. It is the examiner's position that in figure 1 the cross hatching indicates that the materials for end cap 30 and the catheter 16 are at least similar, since both are filled with the same filling material, it is the examiner's position that that cap 32 is more crush resistant than the catheter. In addition, the actual end of the catheter, i.e. the tip, is weakend with respect to the body of the catheter, and as a result, the cap is more crush resistant that the end of the coiled catheter. Alternatively, since end cap 30 is placed in the heart wall and the tip is exposed, it would have been obvious to one skilled in the art to ensure that the cap 30 would be able with withstand more forces. Claim 3 is rejected in that the pressure measurement device is positioned with the catheter across all layers of the heart (see figure 3 and column 5, lines 1-32). Claims 4 and 6 are rejected in that the catheter can be positioned across the heart wall, i.e. the ventricular septum, with the opening in the left ventricle (see column 4, lines 57-69). Claim 5 is rejected in that the opening is in the right ventricle (see column 5, lines 1-11). Claim 7 is rejected in that in figure 7, there is further included a pressure transmitting catheter 462 and a coiled needle used to attach the device to the heart tissue. Claims 8 and 9

are rejected in that depending on where the device is used, the housing 14 may be secured inside or outside of the heart. Claims 10 and 11 are rejected in that the positioning step is done transluminallly, which is surgically. With respect to claim 12, the catheter has a proximal portion 30 and a distal portion 16, where the distal portion is more flexible than the proximal portion. Hence, the proximal portion is more crush proof. With respect to claim 50, the barrier is flush with the end of the catheter. Claims 63 and 65 are rejected in that the barrier is a compliant membrane. Claim6 is rejected in that Pohndorf states that the pressure sensor may be of the type taught by Anderson 4407296, which is incorporated by reference. Anderson 440726 uses a piezoresistive pressure sensor. Hence, so does Pohndorf. Claims 67 and 68 are rejected for the reasons given above.

Claims 2, 13-17, 48, 49, 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf et al in view of Eigler et al 6328699. Pohndorf teaches in column 3, lines 19-27 that the pressure transducer is connected to an implanted monitor. Eigler et al further teaches that it is well known in such a system to have the monitor communicate wirelessly to an external device. Hence, it would have been obvious to modify Pohndorf et al to have the implanted monitor communicate wirelessly to an external device, as it is merely the substitution of a known communication method for another. The remaining features of claims 13-17 were discussed above in the anticipation rejection over Pohndorf. In addition, with respect to claims 48 and 49, the device of Pohndorf may be introduced transvenously (see column 5, line 12). Claims 69

and 70 is rejected in that in Pohndorf, includes a housing with a pressure transducer on the opposite side on the heart wall.

Claims 44 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf et al in view of Brockway et al 6409674. With respect to claim 44, in column 8, lines 19-57, Brockway '674 teaches the equivalence of a coiled stabilizer like that of Pohndorf and a mesh stabilizer that promotes tissue in growth. As such, it would have been obvious to modify Pohndorf et al to use a mesh stabilizer, as it is merely the substitution of one known equivalent stabilizer for another. As such, the housing would have a tissue in growth promoting surface, i.e. the one facing the direction of the coiled needle, and an in growth deterring surface, i.e. the remaining portion of the housing. The device would be positioned as claimed in claim 44. With respect to claim 52, Brockway '674 teaches in column 12, line 37 to column 13 line 4, that it is known to provide a dissolvable material on the tip of a pressure transmission catheter, to ease the transluminal delivery of the pressure sensing device. Hence, it would have been obvious to modify Pohndorf to use a dissolvable material on the tip, to enable easier insertion of the device.

Claims 51 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf et al in view of Brockway et al 4846191. With respect to claim 51, in figure 4, Brockway teaches a barrier recessed from the end of a pressure transmission catheter. Hence, it would have been obvious to modify Pohndorf et al to use such a recessed barrier, as it is merely the substitution of one known functional equivalent catheter for another. Claim 64 is rejected in that the barrier of Brockway is a gel.

Hence , it would have been obvious to modify Pohndorf to use a gel for the barrier, as it is merely the substitution of one known barrier for another.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf et al in view of Brockway et al 6409674 and Zheng 6662045. As discussed above, Brockway teaches alternative securing devices, so as barbs or mesh. Hence, it would have been obvious to modify Figure 7 of Pohndorf to use other fixation devices, as it is merely the substitution of one known equivalent device for another. In addition, Zheng teaches delivering a device into the heart wall, where an introducer sheath is initially around the device, and then both the sheath and the device are advanced through the wall. Hence, it would have been obvious to modify the above combination to deliver the device using an introducer sheath, as it is merely the substitution of one known deliver device for another.

Claims 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf in view of Sommer et al 6132456. Pohndorf teaches that the lead is introduced via any known way for introducing screw in leads for a pace maker. Sommer teaches such a method, where the lead is disposed at the distal end of an introducer sheath, and advanced to the insertion point, where it is screwed into the heart. Hence, it would have been obvious to modify Pohndorf to use such a delivery technique, as it is merely the use of a conventional delivery technique in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit 3735

RLN
December 23, 2007